19 TO ZERO

UNITED AGAINST COVID-19

COVID-19 VACCINATION IN CHILDREN

Contributors: Dr. Noah Ivers, Dr. Nirit Bernhard, Dr. Cora Constantinescu, Dr. Kelly Grindrod, Dr. Jia Hu, Hao Ming Chen, Margaret Pateman

About 19 To Zero

19 To Zero is a multisectoral coalition of health professionals and community members working to shift public perceptions around COVID-19 behaviours and vaccination based primarily at the University of Calgary but national in scope. **Please visit 19ToZero.ca for more info.**

This presentations was prepared by **19 To Zero** in conjunction with **Toronto's Women's College Hospital, University of Toronto Temerty Faculty of Medicine, and Health Commons Solutions Lab**

TEMERTY FACULTY OF MEDICINE
UNIVERSITY OF TORONTO

WCH WOMEN'S COLLEGE HOSPITAL FOUNDATION
Healthcare | REVOLUTIONIZED

19 TO ZERO
UNITED AGAINST COVID-19

HEALTH COMMONS SOLUTIONS LAB

Person putting on hand sanitizer

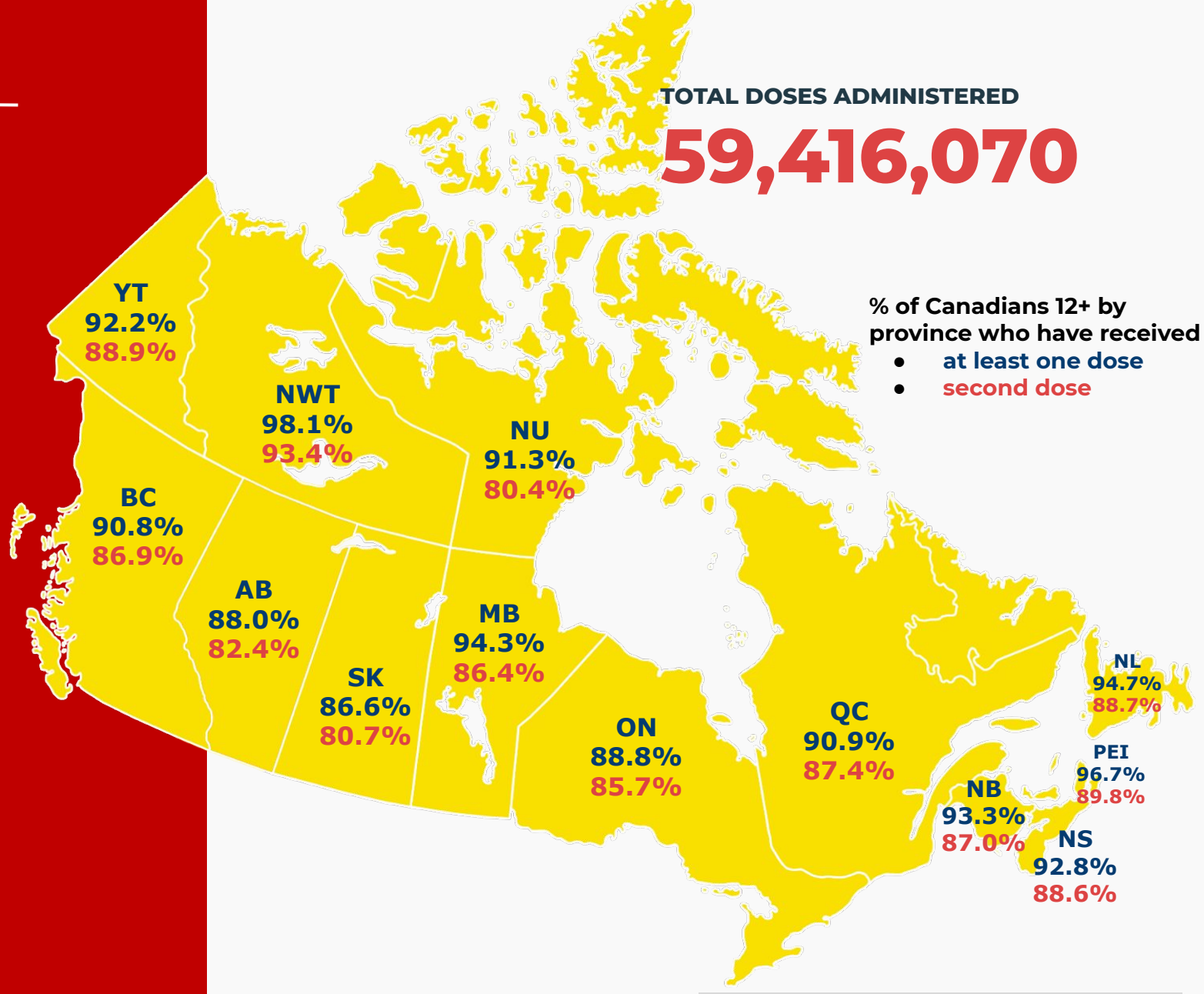
Overview of presentation

1. COVID-19 epidemiology and vaccine uptake in Canada
2. Vaccine uptake preferences among children
3. COVID-19 vaccination in children - the latest science
4. Considerations for vulnerable populations
5. Mitigating pain and anxiety during vaccination

COVID-19 Epidemiology & Vaccine Update

AS OF NOVEMBER 17, 2021:

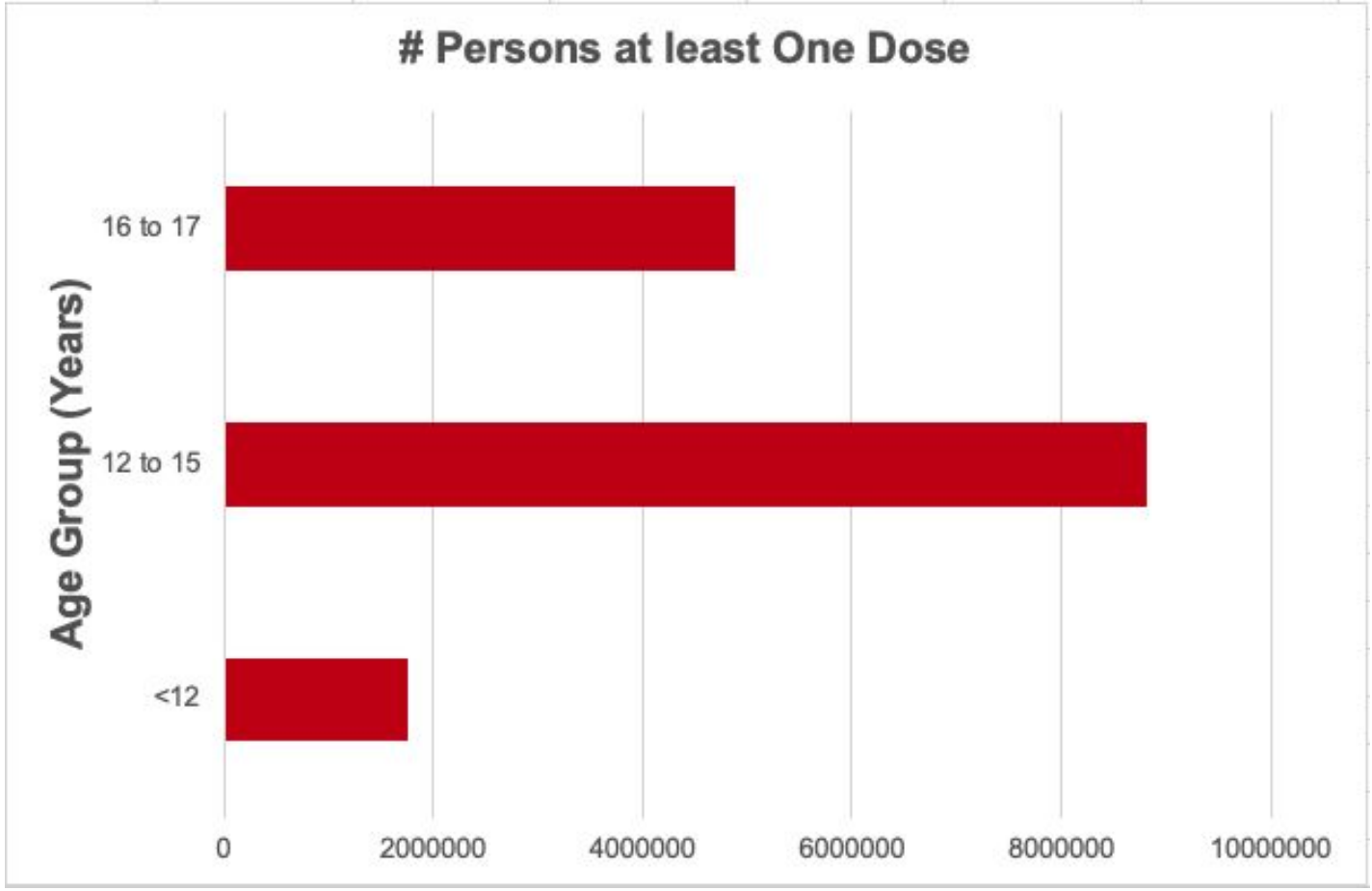
Over 59 million doses have been administered in Canada



Map of Canada

% OF ELIGIBLE POPULATION (12+):
89.6% at least one dose; 85.9% fully vaccinated

In the US more than 1.5 million children <12y have received at least one dose of the Pfizer vaccine



CDC Covid data tracker vaccination demographic. November 17th, 2021

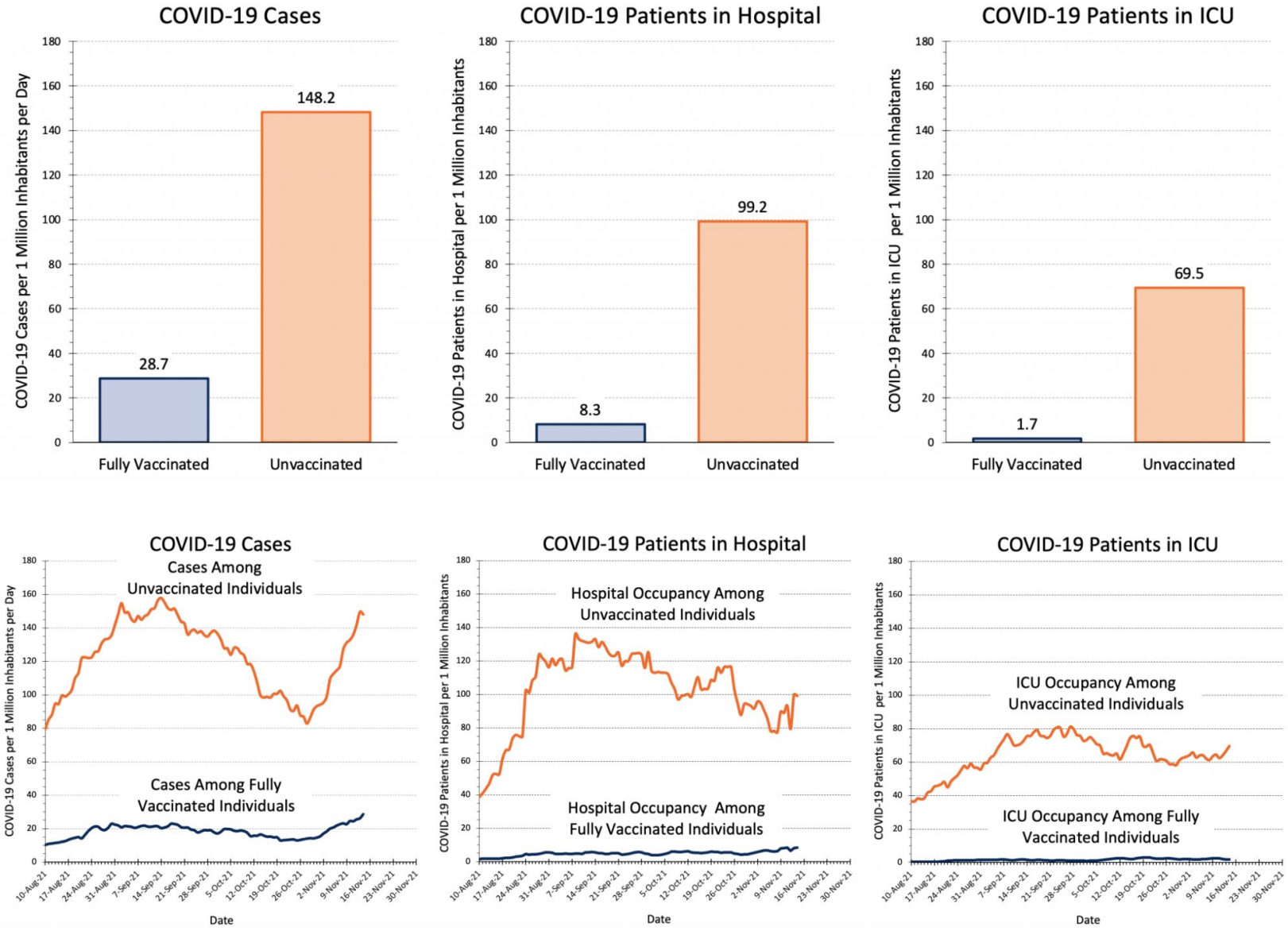
Vaccination rates in Canada are high across most age ranges, except in the 11 and under age range

Table 2. Cumulative percent and number of people who have received a COVID-19 vaccine in Canada by age group and vaccination status, October 30, 2021

Age group (years)	At least 1 dose	Partially vaccinated	Fully vaccinated
0 to 11	0.20% (9,396)	0.04% (2,030)	0.15% (7,366)
12 to 17	86.41% (2,133,043)	6.23% (153,661)	80.19% (1,979,382)
18 to 29	84.75% (5,032,296)	6.75% (400,940)	78.00% (4,631,356)
30 to 39	84.27% (4,520,589)	5.43% (291,267)	78.84% (4,229,322)
40 to 49	87.69% (4,291,341)	4.00% (195,594)	83.70% (4,095,747)
50 to 59	89.64% (4,598,306)	3.02% (154,876)	86.62% (4,443,430)
60 to 69	92.12% (4,458,882)	2.10% (101,762)	90.01% (4,357,120)
70 to 79	93.87% (2,942,089)	1.58% (49,632)	92.28% (2,892,457)
80 and older	94.51% (1,619,860)	2.39% (40,940)	92.13% (1,578,920)

https://health-infobase.canada.ca/covid-19/vaccination-coverage/ accessed Nov 15, 2021

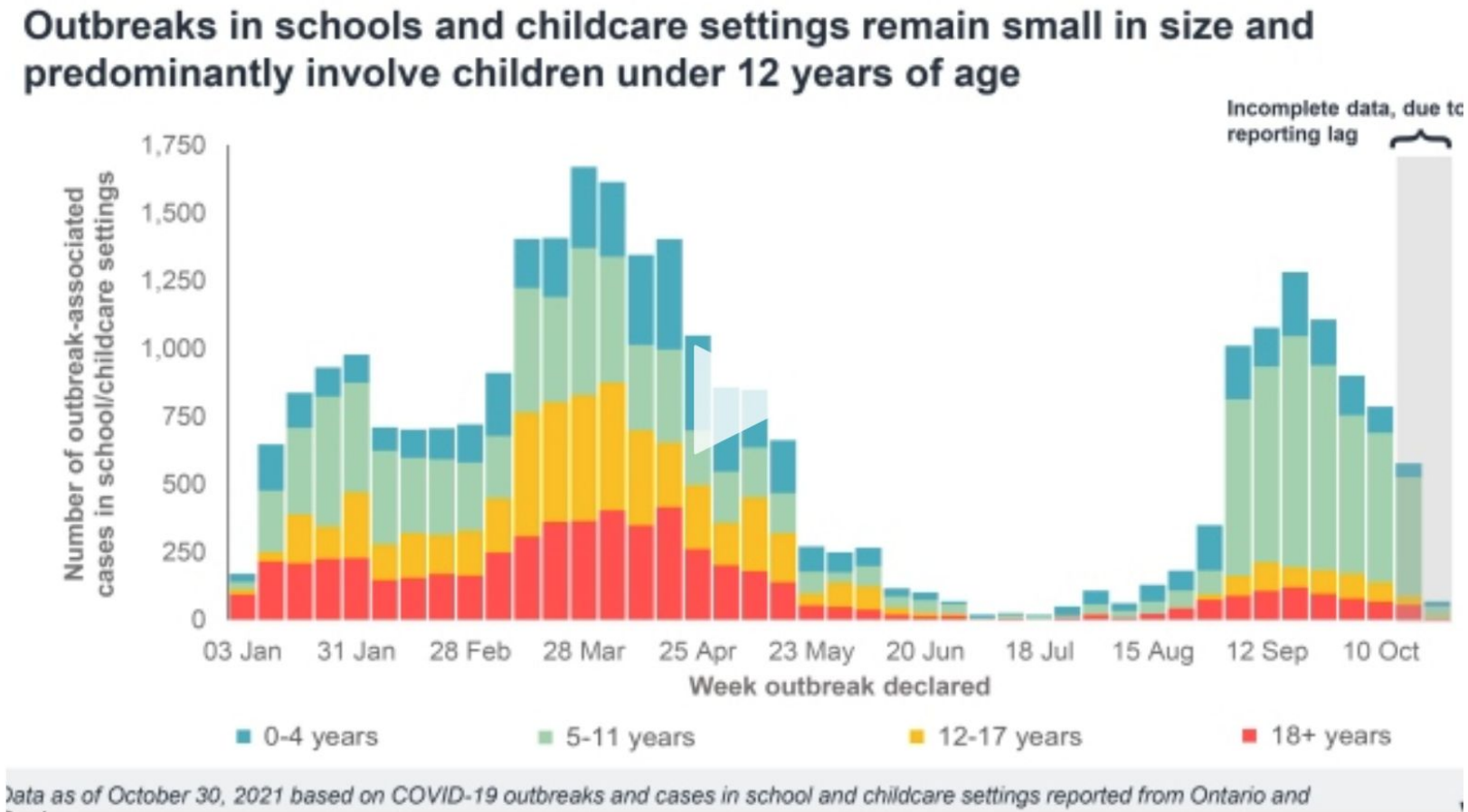
Risks of infection, hospitalization, and ICU are significantly higher among the unvaccinated



Children under 12 now account for highest number of new COVID-19 infections in Canada: PHAC

Hannah Jackson CTVNews.ca Writer
@hannahkeiko | Contact

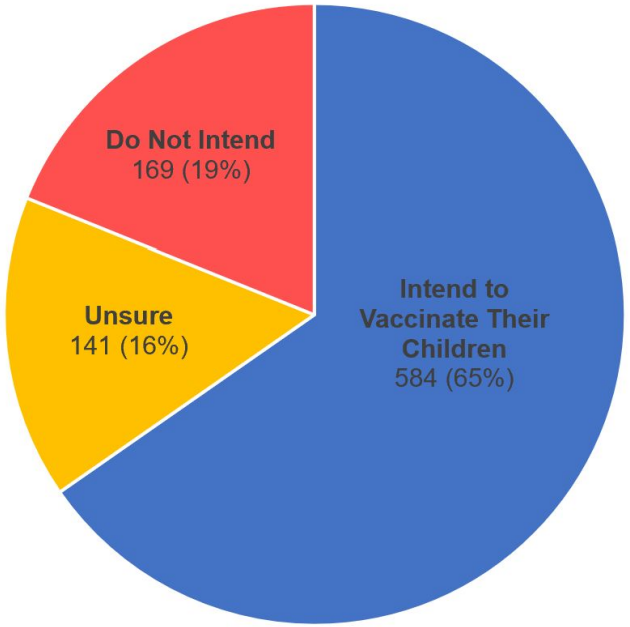
Published Friday, November 5, 2021 9:21AM EDT
Last Updated Friday, November 5, 2021 12:08PM ED



Vaccine Uptake Preferences for Children

About ⅔ of Canadian parents intend to vaccinate their children once a COVID-19 vaccine becomes available:

"Suppose one or more of the COVID-19 vaccines available for individuals 12 and older becomes available to children under 12. Would you have your child vaccinated?" n=594



Source: 19 To Zero National Survey, October 2021

Of those unwilling to vaccinate their children, the following reasons were selected:	Number of Respondents (%)
Children do not need vaccines as they are low risk of severe consequences due to COVID-19	55 (32.7%)
Other safety risks	47 (28.0%)
Natural immunity from previous COVID-19 infection is sufficient protection for my child	20 (11.9%)
Myocarditis risks	16 (9.5%)
Fertility risks	13 (7.7%)
Other reasons	17 (10.1%)

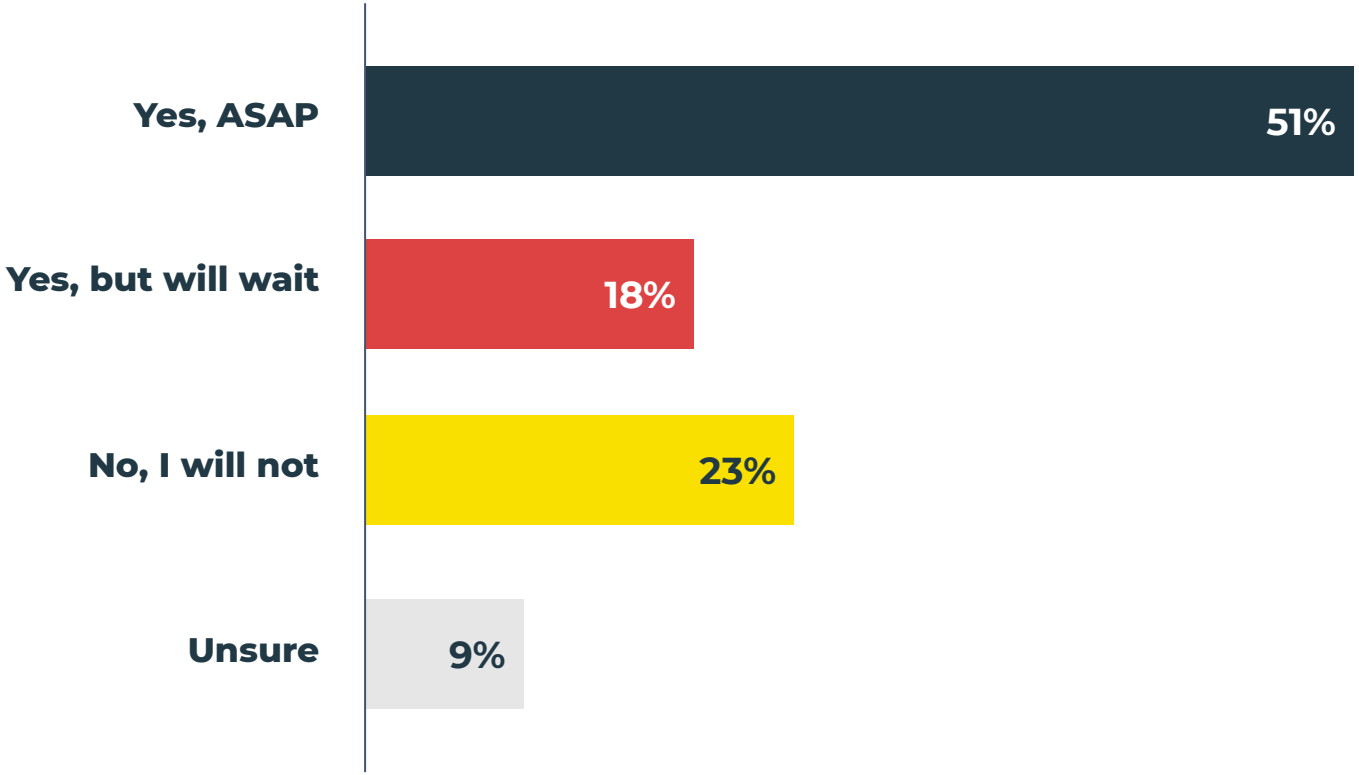
Among those unwilling to vaccine, concerns include:

- Safety - myocarditis, fertility, or other (45%)
- Lack of concern due to low risk of serious COVID-19 in children (33%)
- Natural immunity from prior infection (12%), and
- Other (10%)

Asked another way, only 50% of Canadians would immunize their children ASAP

If a COVID-19 vaccine become available to your child(ren) aged five to 11, will you get them vaccinated?

Among Canadian parents with children in this age range (n = 812)

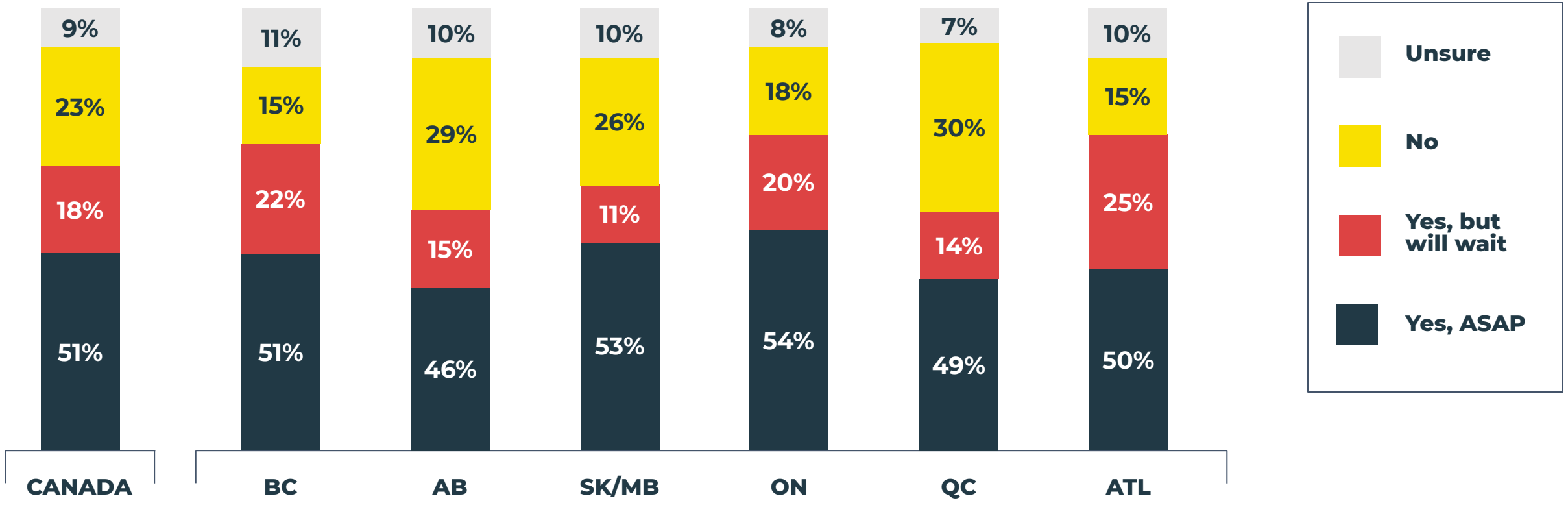


Source: Angus Reid Kids and COVID, Published online October 2021

Refusal to vaccinate is highest in Prairies and QC

If a COVID-19 vaccine become available to your child(ren) aged five to 11, will you get them vaccinated?

Among Canadian parents with children in this age range (n = 812)

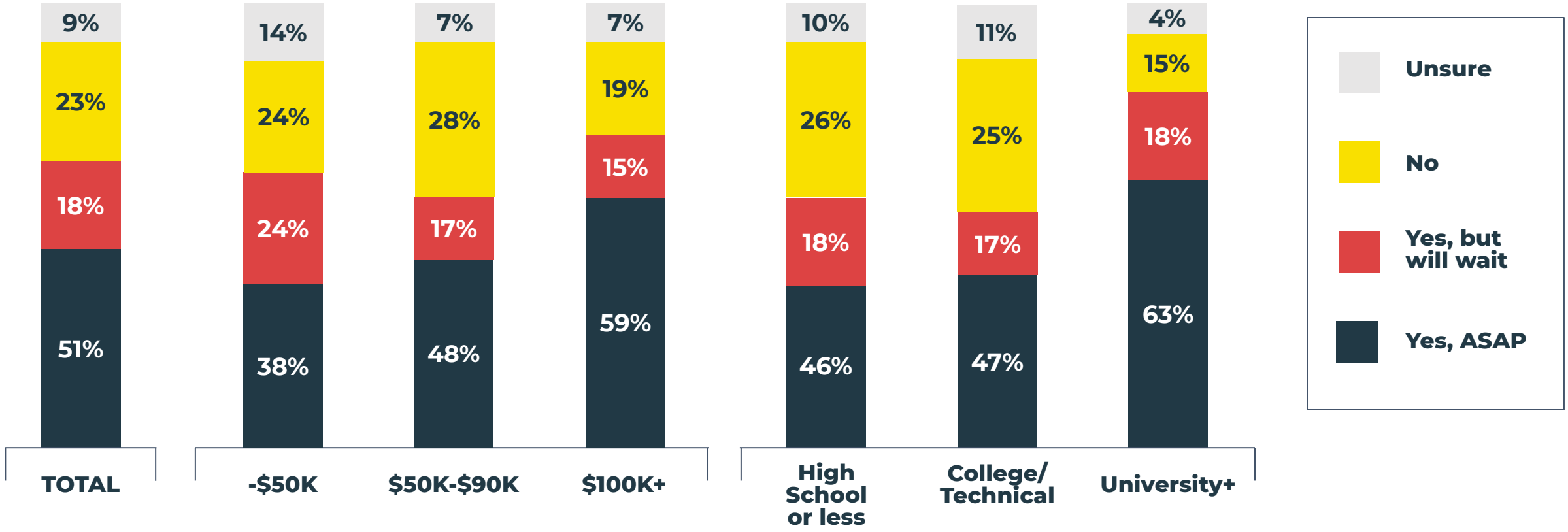


Source: Angus Reid Kids and COVID, Published online October 2021

Willingness to vaccinate children in Canada

If a COVID-19 vaccine become available to your child(ren) aged five to 11, will you get them vaccinated?

Among Canadian parents with children in this age range (n = 812)



Source: Angus Reid Kids and COVID, Published online October 2021

Vaccine Hesitant Parents

- Are more concerned about vaccine safety
- Feel their children are not at high risk of COVID-19 complications
- May feel their kids have already had COVID-19 and have natural immunity
- Don’t trust governments and health agencies
- Have had a negative interaction with healthcare providers in the past
- Have had a negative experience with vaccines in the past

COVID-19 Vaccination in Children - the Latest Science

Why do children need to be immunized?

To protect their health: Some children can become very sick and develop complications or long-lasting symptoms

To prevent virus transmission: Children can transmit the virus to family members and friends even if they are asymptomatic.

To stay in school and continue with other in-person activities: Vaccination reduces the likelihood of school closures and closure of other in-person activities critical to children's' well-being, mental health, and education and development

To protect the broader community: Each child or adult infected provides a chance for the virus to mutate and new variants to develop.

COVID-19 can be severe in children

- Kids make up 20%-30% of COVID-19 cases in most jurisdictions in Canada and USA
  - In USA, more than 3.78M kids have been infected, over 500 kids have died

- **It's not the flu**: COVID-19 is currently in the **top 10 causes of death for children**
  - In Canada and USA, children account for 2% of hospitalizations
  - About 2000 Canadian children have ended up in hospital so far
  - Of those hospitalized, ⅓ had no pre-existing conditions
  - Long-COVID affects 2% of kids

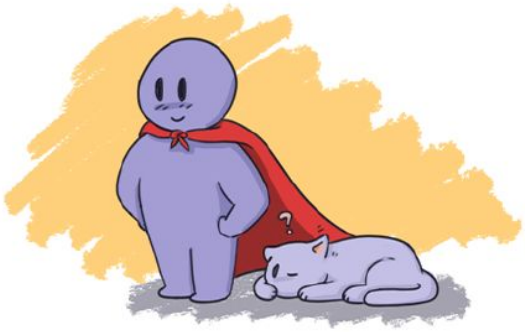
- Did you know: over 99% of Polio cases do not lead to paralysis.

FocusedCovid Communication

UNIVERSITY OF WATERLOO | SCHOOL OF PHARMACY

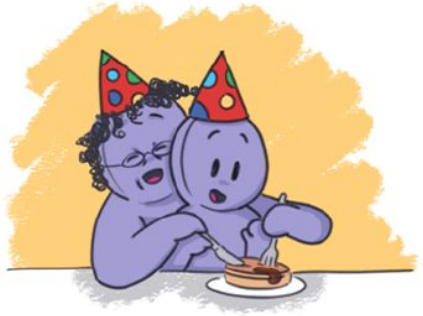
The Benefits of Vaccinating Children

Against Covid-19



Reduced risk of illness

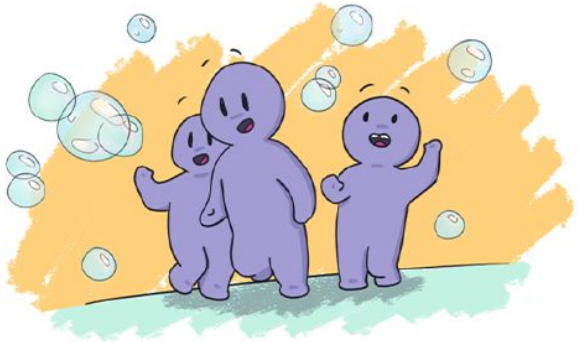
Not needing to miss school due to a case in the classroom



Reduced risk of spread to friends and family with weaker immune systems

Allowing all kids to return to clubs like choir

Allowing all kids to return to fun activities like hockey



Allow all kids to return to being kids again

Let's get all kids back to being kids.

The risks of Covid-19 may be even higher for disabled kids and those with weaker immune systems.
We're not back to normal until everyone is back to normal. Speak to your healthcare provider for advice.

COVID-19 vaccination in children aged 5-11

The **Pfizer BioNTech COVID-19 vaccine has been authorized by Health Canada** for kids 5-11y as a two-dose regimen of 10µg administered 3 weeks apart

Health Canada Statement. Health Canada authorizes use of Comirnaty (the Pfizer-BioNTech COVID-19 vaccine) in children 5 to 11 years of age. (November 19th, 2021)

Pfizer vaccine in children 5-11 years of age - Efficacy

Study Characteristics

- Randomized placebo-controlled Phase 2/3 study
- 4518 kids aged 5-11 (3018 vaccine; 1500 placebo), from Mar - Oct 2021 (when Delta present)
- 2 doses ***10µg*** each, 3 wks apart

Efficacy

- **Vaccine effectiveness was 90.7%** (against confirmed symptomatic COVID-19, assessed starting 7 days after dose 2)

Potential Impact

90% vaccine efficacy →
prevention of ~33600 cases and ~170 hospitalizations over 120 days, per million fully vaccinated children

Vaccines and Related Biological Products Advisory Committee Meeting Document. (2021 Oct 26) FDA.

Pfizer vaccine in children 5-11 years of age - Safety

Side Effects

- Consistent with older children
- Transient, mild side effects 1-2 days after dose with short resolution
- Most common: injection site pain
- No severe adverse effects related to the vaccine (some unrelated were observed, e.g., swallowing a penny!)

Vaccines and Related Biological Products Advisory Committee Meeting Document. (2021 Oct 26) FDA.

Pfizer vaccine in children 5-11 years of age - Myocarditis

Myocarditis Risk?

- **<u>No cases of myocarditis/pericarditis</u>** observed at 3 months post-dose 2 (small sample size)
  - Multiple long-term, five-year safety studies are planned

- Myocarditis rate is 21 per million after 2nd dose for ages 12-15 years (less than 1 in 10,000)
  - **Lower expected rate in 5 to 11 years due to lower dose of vaccine**

Vaccines and Related Biological Products Advisory Committee Meeting Document. (2021 Oct 26) FDA.

NACI recommends two 10µg doses of the Pfizer vaccine may be offered to children 5-11y

- ≥ 8 weeks between doses is recommended as:
  - longer intervals result in higher effectiveness that may last longer
  - may be associated with lower risk of myocarditis
- Children 11 years old who receive the 10µg dose but turn 12 before their 2nd dose may receive a 30µg dose
- Two doses of vaccine may be offered to children who have had COVID-19
- Children who had MIS-C should postpone vaccination until recovery or after 90 days since diagnosis
- The Pfizer vaccine should be given at least 14 days before or after another vaccine when feasible

National Advisory Committee on Immunization (NACI) rapid response: Recommendation on the use of the Pfizer-BioNTech COVID-19 vaccine (10 mcg) in children 5-11 years of age. November 19, 2021

General Side Effects from mRNA vaccines

- Immunization related stress responses such as fainting, fatigue and nausea
  - Treated by managing stress using pain and anxiety reducing strategies for children
- Myocarditis and Pericarditis <1 per 10,000 cases
  - More common after the second dose
  - Symptom onset between 1-7 days after vaccination
  - Mainly adolescent males
  - MAJORITY of cases were mild illness that responded well to non steroidal anti-inflammatory medications (such as ibuprofen) and rest

- **Benefits of COVID-19 vaccinations outweigh the risks of vaccine-caused myocarditis**

Wong, P McCrindle B, et cal. Clinical guidance for youth with myocarditis and pericarditis following mRNA COVID-19 vaccination. Canadian Paediatric Society Practice Point Sept 10 2021. https://www.cps.ca/en/documents/position/clinical-guidance-for-youth-with-myocarditis-and-pericarditis
Moore, D. COVID-19 Vaccine for Children. Canadian Paediatric Society. Position Statement. July 2021. https://www.cps.ca/en/documents/position/covid-19-vaccine-for-children

VAERS Reporting Rate for Myocarditis among males after mRNA COVID-19 vaccine

169,740,953 doses of mRNA vaccine administered to males as of Oct 6, 2021

Highest rates of myocarditis are among male adolescents 16-17y

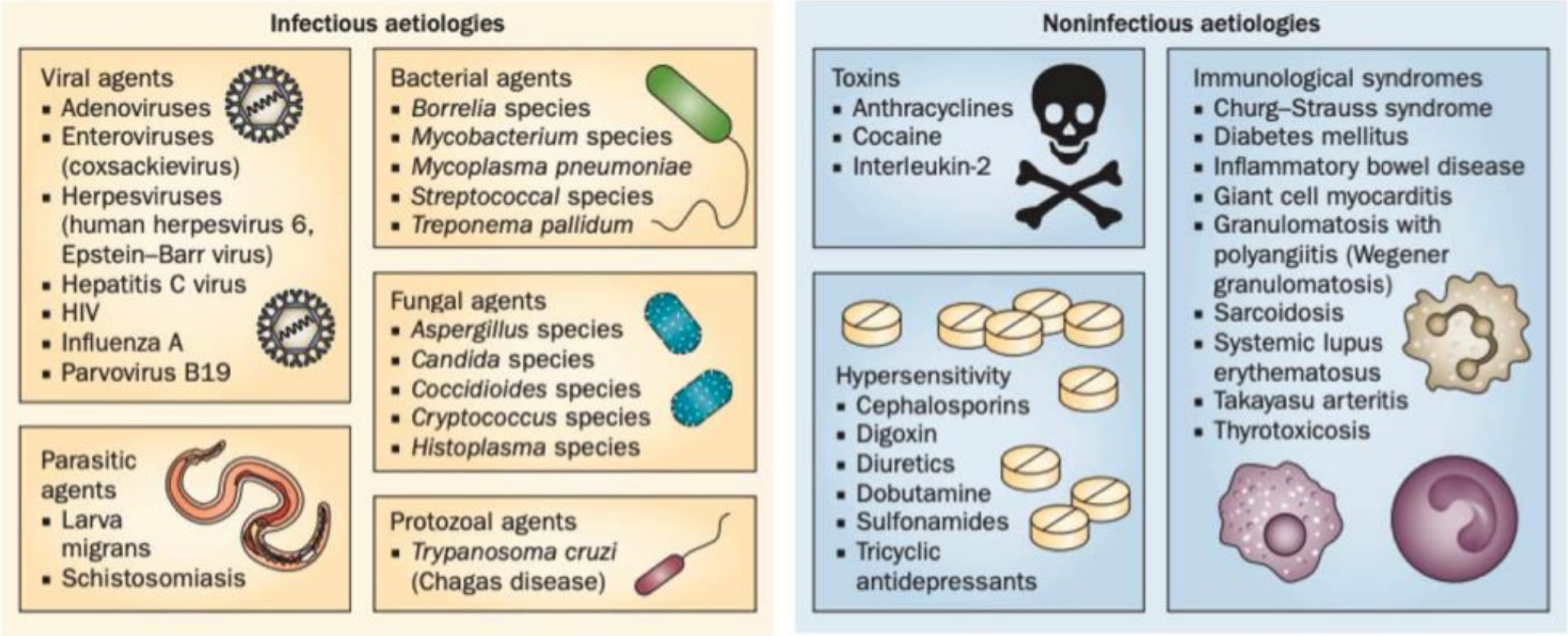
Myocarditis Rate per 1 million doses (n=797)

	Pfizer		Moderna	
	(Males)		(Males)	
Ages	Dose 1	Dose 2	Dose 1	Dose 2
12-15	4.2	39.9		
16-17	5.7	69.1		
18-24	2.3	36.8	6.1	38.5
25-29	1.3	10.8	3.4	17.2
30-39	0.5	5.2	2.3	6.7
40-49	0.3	2.0	0.2	2.9
50-64	0.2	0.3	0.5	0.6
65+	0.2	0.1	0.1	0.3

Reporting rates exceed background incidence

Vaccines and Related Biological Products Advisory Committee Meeting. mRNA COVID-19 Vaccine-Associated Myocarditis (2021 Oct 26) FDA.

Causes of myocarditis include viral infection as the most common cause

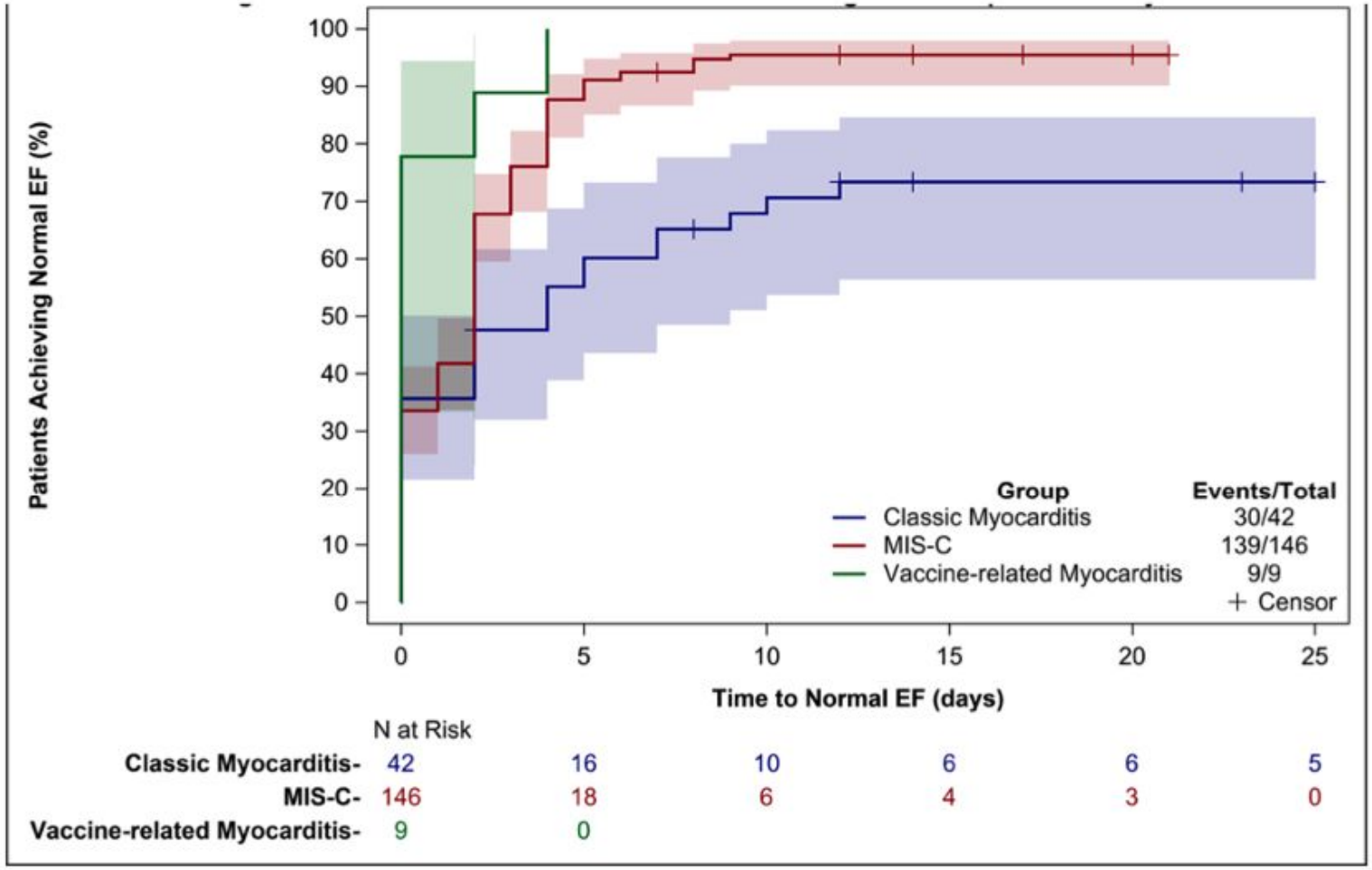


Vaccines and Related Biological Products Advisory Committee Meeting. mRNA COVID-19 Vaccine-Associated Myocarditis (2021 Oct 26) FDA.
Pollack, A. et al. Viral myocarditis—diagnosis, treatment options, and current controversies. Nat Rev Cardiol (2015).

Not all myocarditis is the same

- A retrospective cohort study (preprint) compared patients <21y with classic pre-pandemic viral myocarditis (n=43), MIS-C myocarditis (n=149) and COVID-19 vaccine-related myocarditis (n=9)

- Patients with vaccine-related myocarditis had **prompt resolution of symptoms and improvement in cardiac function**



Vaccines and Related Biological Products Advisory Committee Meeting. mRNA COVID-19 Vaccine-Associated Myocarditis (2021 Oct 26) FDA.
Patel, T. et al. Comparison of MIS-C Related Myocarditis, Classic Viral Myocarditis, and COVID-19 Vaccine related Myocarditis in Children. medRxiv 2021

ACIP: benefits outweigh risks for vaccination and recommends the vaccine to children 5-11y

COVID-19 in children is a major public health problem

- 1.9 million COVID-19 cases & 8,300 hospitalizations among U.S. children 5–11y as of Oct 10, 2021
- 5,217 total cases of MIS-C (44% in 5-11y)
- Children 5–11y represent a growing proportion of new COVID-19 cases - 10.6% of infections week of Oct 10
- COVID-19 ranks as the 8th leading cause of death in 5-11y age group
- Delta-wave surges of pediatric COVID-19 hospitalizations occurred even with a significant proportion of children previously infected

Woodworth KR et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Children Aged 5–11 Years — United States, November 2021. MMWR Morb Mortal Wkly Rep 2021

ACIP: benefits outweigh risks for vaccination and recommends the vaccine to children 5-11y

Risk of Myocarditis

- The observed myocarditis risk is highest in males aged 12–29y. No cases of myocarditis were reported in the Pfizer trial in 5-11y.
- The baseline risk for myocarditis is much higher in 12–17y than in 5–11y. Myocarditis in adolescents might not predict risk for myocarditis in younger children.

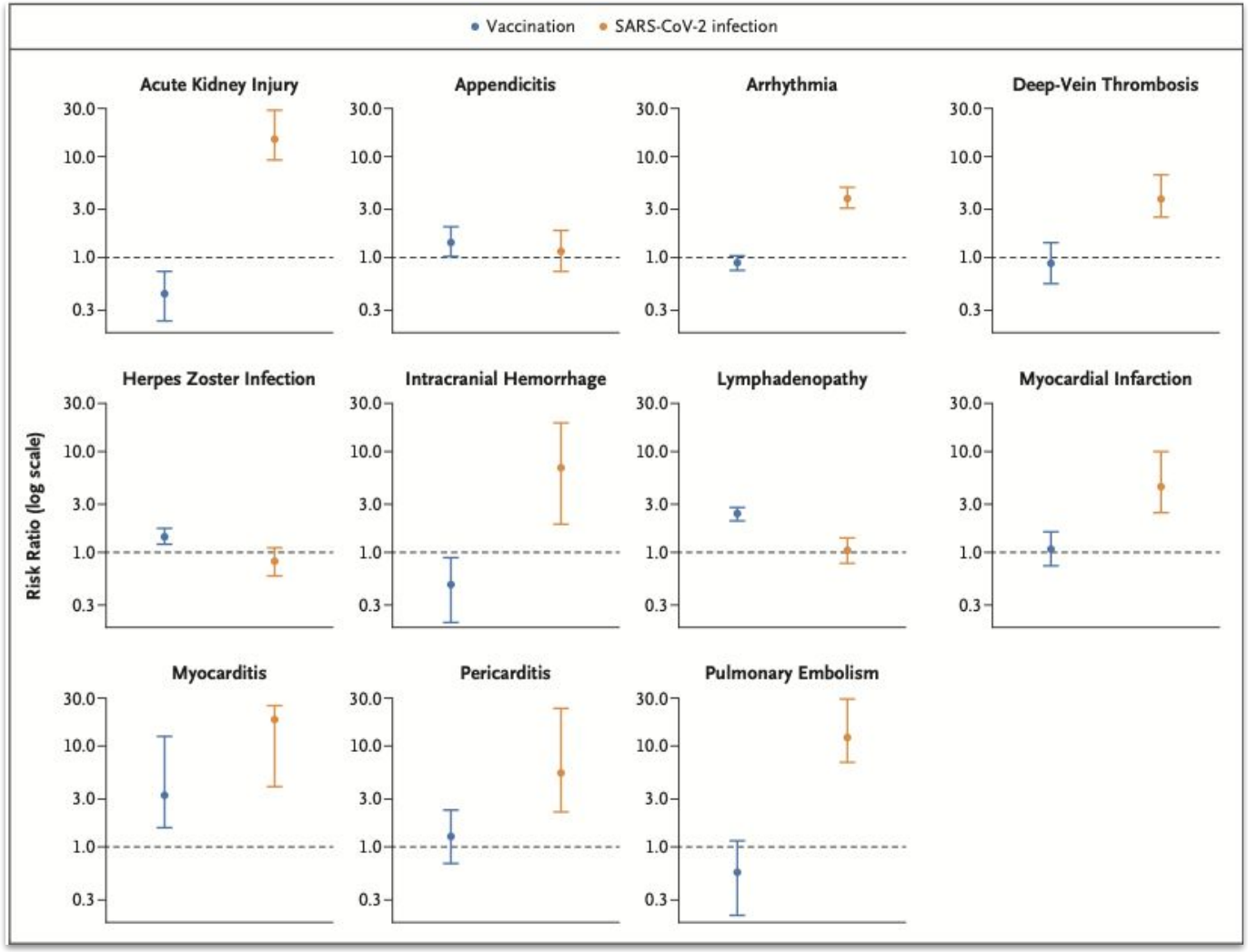
Vaccination is important to protect children against COVID-19, even in those previously infected, and to reduce community transmission.

Woodworth KR et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Children Aged 5–11 Years — United States, November 2021. MMWR Morb Mortal Wkly Rep 2021

Adverse Events - *MUCH LOWER* for vaccination than for SARS-CoV-2 Infection (adult data)

SARS-CoV-2 infection was associated with a significantly increased risk of myocarditis, pericarditis, arrhythmia, deep-vein thrombosis, kidney injury, pulmonary embolism, myocardial infarction, intracranial hemorrhage, and thrombocytopenia compared to those who received the **COVID-19 vaccine**.

Choosing to gain immunity from infection rather than from vaccination is not a good bet



Barda N, Dagan N, Ben-Shlomo Y, et al. Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting. *N Engl J Med*. 2021;10.1056/NEJMoa2110475.

Other vaccine preventable diseases:

Deaths per year prior to recommended vaccines

	Hepatitis A[1]	Meningococcal (ACWY)[2]	Varicella[3]	Rubella[4]	Rotavirus[5]	COVID-19
Age	<20 years	11–18 years	5–9 years	All ages	<5 years	5–11 years
Time period	1990–1995	2000–2004	1990–1994	1966–1968	1985–1991	Oct 2020–Oct 2021
Average deaths per year	**3**	**8**	**16**	**17**	**20**	**66**

MODERNA's vaccine in children 6-12 years of age - early press release information

- Moderna announced the vaccine is safe and highly effective in children aged 6-12y using a two dose regime of 50 µg, given 28 days apart. (Phase 2/3 KidCOVE)
- The vaccine elicited a strong immune response evidenced by robust neutralizing antibody levels comparable to young adults.
- The vaccine was well-tolerated. AE were mild to moderate.
- Most common AE were fatigue, headache, fever and injection site pain.
- Moderna plans to submit results to the US FDA and other regulatory agencies in the near term.

Moderna Announces Positive Top Line Data from Phase 2/3 Study of COVID-19 Vaccine in Children 6 to 11 Years of Age. October 25, 2021

Vaccine Trials in Younger (6 months to 5 years of age) Children - expected soon

Vaccine Clinical Trial	Trial Details	Results Timeline
Pfizer NCT04816643	• Recruiting; 6 mos - 11 y/o in 3 age groups (5-11y; 2-4y; 6-23m, in sequence); n=4644 • Phase 1 is dose finding (10/20/30 mcg mRNA) • Phase 2/3 is safety, immunogenicity, clinical efficacy - bridging trial	Results for 6 mo - 5 year olds expected in early 2022
Moderna NCT04796896	• Recruiting; 6 mos - 11 y/o in 3 age groups (6-11y; 2-5y; 6-23m, in sequence); n=13275 • Phase 1 is dose finding (25/50/100 mcg mRNA) • Phase 2/3 is safety immunogenicity, clinical efficacy - bridging trial	Results for 6-11y released Oct 2021 (press release); results for 5 and under expected later

Considerations for Vulnerable Populations

Study led by Health Commons Solutions Lab

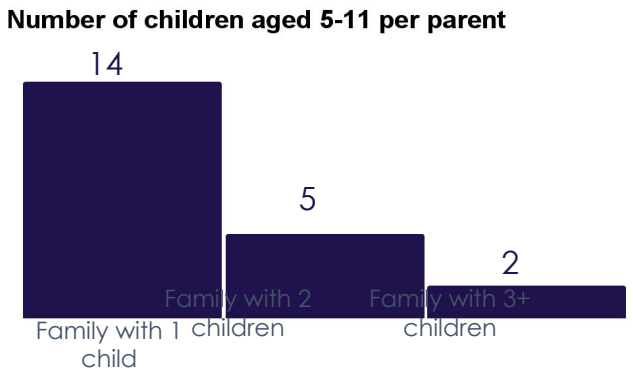
The voices we heard from

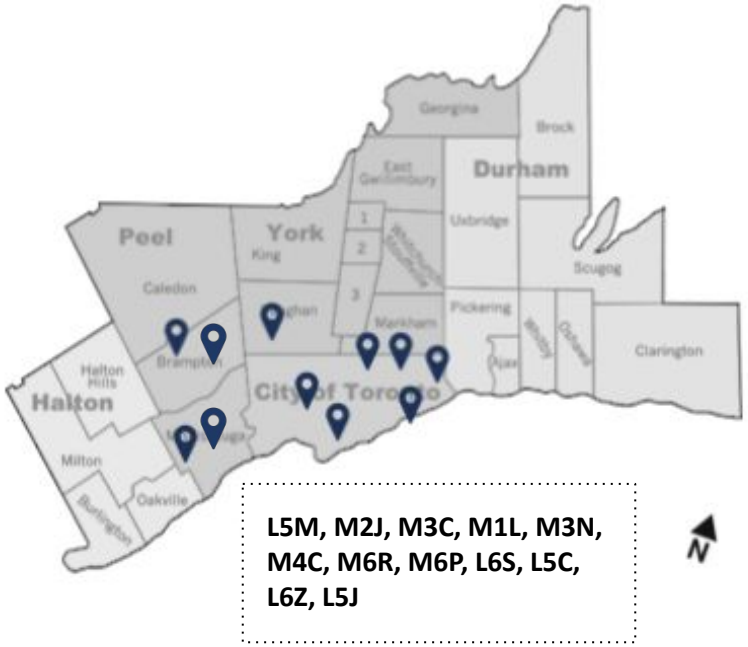
29 community members between the ages of 28-46 (96% female, 4% male) from multiple neighbourhoods across the **High Priority Communities** **in Ontario** shared their perspectives with us

- 22 participants provided voluntary socio-demographic information including the following self-identified ethnicities:
  - → African, African/indigenous, Arab, Black, Black Canadian (Jamaican), Caribbean, Caucasian, Hispanic, Indian, Karen (Myanmar/Burma), Middle Eastern, Lebanese, South Indian

Approximately **40 community ambassadors** from the High Priority Communities Strategy in Ontario also informed this work through a group discussion on vaccines in children

While the intention of this engagement was to capture the voices of marginalized groups we did have some gaps (Indigenous parents and children, and parents and children with physical and intellectual disabilities)





Community members represented postal codes from Peel, Toronto, and York region

Parents' experiences during the pandemic are influencing their decision making

- There remain communities, families and children who have been differentially impacted by the pandemic, specifically low income and racialized communities. This is the context that "primes" the conversation for many of the parents we spoke to

- Parents who have questions or concerns about the vaccine feel coerced by the mandates and public messaging and this is eroding trust - **running the risk of entrenching a "no"**

- Many do not trust the motivations behind the public health messaging for vaccines for children under 12

- Wholistically support parents with more than vaccine information
  - Support schools and children's programming with **policies that ensure inclusion of unvaccinated children, maintain their safety, and leave the door open for vaccination**

HEALTH COMMONS SOLUTIONS LAB

Provide factual, accessible, clear information to answer parents questions about COVID, vaccines, and safety measures now and in the future

- In the context of an "emerging picture" parents see themselves as capable of making an informed choice if they have the right information
  - Transparently and neutrally relay scientific advice and updated guidance in real time
  - Normalize changes in advice as a part of the process so that they are not seen as inconsistencies or mistakes
  - Convey information about the benefits and risks of the vaccine vs. COVID for children in a balanced way
- Provide data showcasing the local impact of participating in vaccination and celebrate the progress of increasing community safety
- Be transparent about the rationale behind new phases of safety protocols and vaccination rolls out. Offer detailed information about the factors being considered (public health, economic recovery, vulnerable populations, pediatric consent laws)

HEALTH COMMONS SOLUTIONS LAB

Tips

How to have productive conversations

Recruit their sense of agency and their individual motivations

- Providing information in neutral way and then shifting to motivational interviewing strategies will help people explore their own reasons for choosing to have their children vaccinated
- Common approaches such as: using the “all in this together” positioning, challenging or interrogating assumptions or attempting to sway in the conversation; **are more likely to increase resistance and entrench an individual's beliefs**

Motivational interviewing approach (Adapted from NYT Article):

- **Be curious** and establish a friendly tone in the conversation
- **Acknowledge that there is a lot of conflicting information** out there and that **people start out with different levels of trust** in governments, pharma and institutions
- Decide that the goal is to **open** the conversation and create a space where parent’s can explore their beliefs without challenging their identities. Assume that the first conversation may not be the last

Mitigating Pain & Anxiety During Vaccination

Pain is an important factor in vaccine uptake.

- Meta-analysis, 35 studies included in the final analysis.
- Avoidance of influenza vaccines related to needle fear in influenza vaccine occurred in:
- 16% of adult patients.
- 27% of hospital employees.
- 18% of workers at long term care facilities.
    - Important factor in COVID-19 vaccines as they are reported to have more pain and injection site reactions than influenza vaccines.

5 Commitments to Comfort Principles

1. **Create a Comfort Plan**
   a. Ask if the person being vaccinated has preferences or concerns with their comfort management and offer choice when able (e.g., preferred pain management strategies, comfort positions).

2. **Use Numbing Cream**

3. **Use Simple, Positive Language**
   a. This makes it more likely a person will return for vaccinations in the future.
   b. Communicate in a way that reduces fear and distress prior, during, and after the immunization.
      i. Avoid saying “it will be over soon” or “it will be OK” or words that amplify fear or pain, for example “this is a really painful shot”.
      ii. Talk about what is going well/went well, for example “you did a great job relaxing your arm”
      iii. After the immunization is over tell the individual “they did well”, or “by doing this today you are saving lives/keeping yourself and others safe.

4. **Use Comfort Positions: Upright comfortable position**
   a. If they feel faint or has a history of fainting with needles:
      i. encourage alternating muscle tension and relaxation (for 15 seconds increments), or have them lie down.

5. **Shift Attention**
   a. Examples: using electronics (music/games), slow deep breathing, asking ‘small talk’ friendly questions, or focusing on a picture or poster on the wall.